

REMARKS

The Claims (claims 1 and 2) have been amended in this paper. Claim 3 has been cancelled. Upon entry of the within amendments, claims 1, 2, and 4-7 will be pending for further examination.

Claim 1 has been amended to more clearly define the subject matter of the present invention. Support for amended claim 1 can be found in original claim 3 and throughout Applicants' specification, for example, lines 21-23 of page 4, lines 13-18 of page 5, and lines 15-18 of page 7 of the application as originally filed.

Claim 2 is amended to correct an informality.

No new matter is added by virtue of the within amendments.

Applicants respectfully request reconsideration and withdrawal of the rejections directed to claims 1, 2, and 4-7, all of which Applicants respectfully submit are in condition for allowance (per the discussion below).

Rejection under 35 U.S.C. §102 (b)

Claim 1, 2, and 5-7 are rejected under 35 U.S.C. §102(b) over Tsuruda *et al.* (WO 01/68061, also as U.S. 6,924,410; hereinafter as "Tsuruda").

Without conceding the validity of the Examiner's allegation and solely for facilitating the prosecution of the present application, independent claim 1 has been amended.

In particular, Tsuruda does not teach or suggest a patch in accordance with the present invention that comprises a polyester backing, of which ultraviolet transmittance is not more than 2.0% under the condition of 3.0 mW/cm² of ultraviolet intensity, as recited in independent claim 1. Indeed, Tsuruda fails to teach or suggest the features of the present invention in any manner sufficient to sustain the rejection.

For at least the foregoing reasons, it is respectfully submitted that the rejection under 35 USC §102 (b) is properly withdrawn. For example, see *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978) ("[r]ejections under 35 U.S.C. §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art.")

Rejection under 35 U.S.C. §103(a)

Claims 1 and 3 are rejected under 35 U.S.C. §103(a) over Tsuruda.

The rejection is traversed.

Tsuruda fails to teach, suggest or predict the patch as recited in the amended claims. Also, as noted above, independent claim 1 has been amended to further define the features of the invention.

Moreover, Applicants respectfully submit that Tsuruda and the present invention correspond to two fundamentally different patches characterized by two very distinct ultraviolet intensities. In particular, the ultraviolet intensity taught by Tsuruda is 0.14 mW/hr/cm², whereas the present invention is under the condition of 3.0 mW/cm² of ultraviolet intensity.

Tsuruda discloses a backing having a light transmittance of not more than 26%, or preferably not more than 15%, at an ultraviolet intensity of about 0.14 mW/hr/cm² (see column 4, lines 19-27 of Tsuruda). Tsuruda does not teach or suggest any patch having a backing of which the ultraviolet transmittance is not more than 2.0% at an ultraviolet intensity of about 3.0 mW/hr/cm².

Moreover, Applicants submit that the phototransmission taught by Tsuruda is different from that of the present application. The examples in Tsuruda and the present application clearly demonstrate that difference. For instance, Example 6 of Tsuruda and Comparative Example 2 of the present application teach two substantially identical backing preparations. The phototransmission rate of the backing in Tsuruda's

Example 6 was 1.8%, as compared to the backing in Comparative Example 2 which was 2.83%, according to the respective results. The difference between the two is a result of the difference in the respective ultraviolet intensities, of which the former was 0.14mW/hr/cm^2 , and the latter was about 3.0mW/cm^2 . Accordingly, the phototransmission taught by Tsuruda is not equivalent to the ultraviolet transmittance measured in accordance with the present application.

Further, Applicants submit that the record shows no reason why one skilled in the art would modify Tsuruda to arrive at the present patch, wherein (1) a polyester backing having ultraviolet transmittance not more than 2.0% under the condition of 3.0mW/cm^2 of ultraviolet intensity; (2) containing a nonsteroidal anti-inflammatory drug; and (3) the backing contains a hydroxyphenylbenzotriazole derivative represented by the general formula(1) as recited in claim 1. In *Eisai Co., Ltd v. Dr. Reddy, Labs., Ltd*, 2007-1397, slip op. at 8 (Fed. Cir. Jul. 21, 2008)(“*Eisai*”), the CAFC stated that “KSR presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound.” (citing *Takeda Chem. Indus. v. Alphapharm Pty., Ltd*, 492 F.3rd 1350, 1357 (Fed. Cir. 2007))(and holding at 7, that the prior art taught compounds with fluorine-substituted groups that increased lipophilicity, whereas “the record... shows no reason for a skilled artisan to begin with [a prior art compound] only to drop the very feature, the fluorinated substitute, that gave this advantageous property”).

Tsuruda thus fails to teach or suggest the subject matter of the present claims for at least the above reasons. By way of further explanation:

First, as previously discussed, Tsuruda and the present invention are directed to two fundamentally different patches, as evidenced by the different conditions of ultraviolet intensity used and different light transmittances (phototransmittance and ultraviolet transmittance) measured.

Second, Tsuruda fails to provide any motivation or suggestion to modify the preparation described therein to reach the present invention.

Third, Applicants have surprisingly found that patches of the present invention lower the ultraviolet transmittance of the backing, while exhibiting excellent drug delivery effects even when exposed to the direct rays of the sun in a season of high ultraviolet dose (see page 4, lines 8-13 of the present application). At the claimed conditions, patches of the present invention may be suitably and favorably used for application of a nonsteroidal anti-inflammatory drug (NSAID) which is low in stability toward ultraviolet light. In addition, because of the superiority of the present invention, even when the pressure-sensitive adhesive layer contains no ultraviolet absorbent, there is no degradation of the pressure-sensitive adhesive layer and there is excellent stability and safety; this is due to the fact that there is no contact to the skin of the ultraviolet absorbent itself (see page 4, lines 13-20 of the present application). In contrast, Tsuruda does not teach or suggest any such effects being rendered by the specific combinations as presently claimed. Nor does Tsuruda provide any motivation or suggestion to achieve such technical effects. Indeed, because Tsuruda is dealing with a much lower ultraviolet dose, it would not be possible for the skilled artisan to predict the unexpected and extraordinary technical results of the present invention in view of Tsuruda's disclosure, nor would there be any motivation or suggestion in that regard.

It is well-known that to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior

art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143.

There is no suggestion or motivation, either in Tsuruda or in the knowledge generally available to one of ordinary skill in the art, to modify the cited art to make the claimed invention, nor is there a reasonable expectation of success in the art to achieve the unexpected results of the present invention.

In view thereof, Applicants submit that the present invention is patentable over Tsuruda. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a) are requested.

Claims 1 and 4 are rejected under 35 U.S.C. §103(a) over Tsuruda in view of Cordes *et al.* (WO 97/232,227; hereinafter "Cordes").

The rejection is traversed.

Applicant respectfully submits that the combined disclosures of Tsuruda and Cordes still fail to teach, suggest or predict the patches recited in the present claims.

Cordes is relied upon for its alleged disclosure of a polyester backing layer with about $96 \pm 5 \text{ g/m}^2$. However, given the deficiencies of Tsuruda (discussed above), the combination is still insufficient to sustain the rejection. Cordes cannot remedy the deficiencies of Tsuruda. As such, even in combination, the cited art fails to teach or suggest a patch with ultraviolet transmittance not more than 2.0% under the condition of 3.0 mW/cm^2 of ultraviolet intensity, and within the weight of 100 g/m^2 to 130 g/m^2 as recited in the present claims.

Moreover, Cordes does not disclose a polyester backing layer with a weight per area of $96 \pm 5 \text{ g/m}^2$. It only discloses a film of a matrix weighing $96 \pm 5\% \text{ g/m}^2$ as dry weight and corresponding to 1.25 g estradiol and 8.32 g NETA per m^2 of the dry matrix.

According to this description, the weight of the polyester backing layer is about 91.23 g/m² at most.

As such, the present invention is clearly distinguishable from the art cited in Tsuruda and Cordes. Consequently, the skilled artisan would not arrive at the present invention based on their disclosures, even in combination.

Double-Patenting Rejections

For the sake of brevity, these rejections are summarized and discussed in combination as follows:

Claims 1, 2, 5 and 6 are non-provisionally rejected over US Patent No. 6,924,410 (hereinafter "the '410 patent").

Claims 1,2, 5, and 6 are provisionally rejected over co-pending US Patent Application No. 10/584,739.

It is respectfully submitted that the non-provisional double patenting rejection over the '410 patent is overcome by the amendments made to claim 1. The '410 patent teaches a patch measured under the condition of an ultraviolet intensity of 0.14 mW/hr/cm², whereas the present patch has a backing of which ultraviolet transmittance is not more than 2.0% under the condition of 3.0 mW/cm² of ultraviolet intensity. Further as previously discussed, the backing of the '410 patent does not have less than 2.0% phototransmittance as required by the present invention (e.g., the lowest number 1.8% in the '410 patent is equivalent to 2.83% and only if measured under the conditions of the present invention).

With regard to the provisional double patenting rejection over U.S. Patent Application No. 10/584,739, since it is a "provisional" rejection, it is respectfully requested that pursuant to MPEP §804 and §822.01, it be withdrawn so that the present application may proceed to allowance.

CONCLUSION

In view of the above amendments and remarks, Applicant believes the pending application is in condition for immediate allowance.

FEE AUTHORIZATION

No fees are believed to be due. The Commissioner is authorized to charge any fees associated with this submission to our Deposit Account, No. 04-1105, Reference 64286(49811). Any overpayment should be credited to said Deposit Account.

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Respectfully submitted,

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